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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Matthias Rath

11957/20

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26646

7590

03/18/2004

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/077,283	Applicant(s) RATH, MATTHIAS	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Group I, claims 1-3 and 8-9 on 2/18/04 is acknowledged. The traversal is on the ground(s) that because groups are classified in the related class and subclass, undue burden would not be imposed on the examiner.

However this is not found persuasive because for purposes of the initial restriction requirement a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. No such showing or evidence has been provided. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. An undue burden would ensue from the examination of multiple compositions which have distinct characteristics and a process of use. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

Claims 4-7 and 10-22 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "and/or precursors and cofactors thereof", since ultimately carbon is a precursor of any organic compound and the

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nature of "cofactors" cannot be readily determined in this context. Also the nature of "chemical substances" in this context is unclear. Do applicants mean "chemical compounds". Substances generally denote mixtures of undetermined constitution.

Claim 9 is vague, indefinite and improper in the recitation of "is provided to a human subject in the form of", given that this appears to be intended as a process claim, whereas claims 1-7 on which it depends are composition claims.

Claims 8 and 9 are incomplete in depending on non-elected claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Blass.

The claims are directed to a composition comprising two or more chemical substances of Krebs cycle, wherein the chemical substances are intermediates of the cycle and/or precursors and cofactors thereof. See, e.g., Example 3, wherein a composition comprising malic acid and glucose is disclosed. Glucose is a precursor of Krebs cycle intermediates.

Therefore, the reference anticipates the claims.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Umezama.

The claims are directed to a composition comprising two or more chemical substances of Krebs cycle, wherein the chemical substances are intermediates of the cycle and/or precursors and cofactors thereof. See, e.g., Table IV, wherein compositions comprising leucine and/or glucose and Krebs cycle intermediates such as pyruvic acid, citric acid, α -ketoglutaric acid are disclosed. Leucine and glucose are precursors of Krebs cycle intermediates.

It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed

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composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Therefore, the reference anticipates the claims.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bourgeron *et al.*.

The claims are directed to a composition comprising two or more chemical substances of Krebs cycle, wherein the chemical substances are intermediates of the cycle and/or precursors and cofactors thereof. See, e.g., Table I, wherein compositions comprising Krebs cycle intermediates such as fumarate and α -ketoglutarate are disclosed. Leucine and glucose are precursors of Krebs cycle intermediates.

It is noted that the reference does not teach that the composition can be used for improving bioenergy metabolism, however, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the disclosed composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Claims 1-3 and 8-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Richmond *et al.*.

The claims are directed to a composition comprising two or more chemical substances of Krebs cycle, wherein the chemical substances are intermediates of the cycle and/or precursors

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and cofactors thereof. Richmond *et al.* discloses a composition comprising at least one member of the citric acid (Krebs) cycle and mixtures thereof in conjunction with at least magnesium and calcium. See, e.g., col. 2, line 66 through col. 3 and claim 1.

Therefore, the reference anticipates the claims.

Claims 1-3 and 8-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Waterman *et al.*.

The claims are directed to a composition comprising two or more chemical substances of Krebs cycle, wherein the chemical substances are intermediates of the cycle and/or precursors and cofactors thereof. Waterman *et al.* discloses a composition comprising at least one member of the citric acid (Krebs) cycle and mixtures thereof in conjunction with a food carrier containing at least vitamins and minerals. See, e.g., col. 4, lines 20-28, Trials and claims.

Therefore, the reference anticipates the claims.

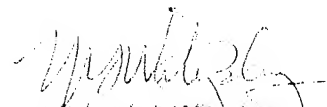
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
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